

Rejections under 35 USC 102(f) and 102(e)/103(a)

The Examiner maintained the rejection on claims 4, 6, 8 and 22-26 under 35 U.S.C. 102(f) because the claims drawn to isolated nucleic acid molecules consisting of SEQ ID Nos: 853-855 of instant invention match absolutely with the SEQ ID Nos: 85, 86 and 87 of copending application NO: 09/618,893, and with SEQ ID Nos: 16753 and 16574 of copending application NO. 09/614, 150 (in the Office Action, the Examiner mistakenly stated SEQ ID NO: 1314-1316).

Applicants respectfully disagree. These two applications are not the prior art against the present application. The present application claims priority at least to one provisional application filed on March 3, 2000 (Application NO: 60/187, 241). The SEQ ID NOs: 853-855 of the present invention correspond to SEQ ID NO: 1314-1316 in the priority application NO: 60/187, 241 filed on March 3, 2000.

Although applications 09/618,893 and 09/614,150 claimed a series of earlier priority dates in provisional applications, however, the sequences absolutely matching to the claimed sequences of the instant invention were not disclosed earlier than March 3, 2000, in any of provisional applications of 09/614, 150 or 09/618,893. Therefore, application NO: 09/618,893 and application NO. 09/614, 150 do not constitute prior art to the present application. The rejection should be withdrawn.

For the same reason, Applicants respectfully request the withdrawal of the rejection under 35 U.S.C 102(e). Because the sequences in the claims of the present application were filed on March 3, 2000, and the sequences in application NO: 09/614,150 that have absolute match to the claimed sequences of the instant invention were disclosed later, if not the same time, than the priority date of the present invention, application NO. 09/614, 150 (the Venter application) is no longer prior art to the present invention.

Examiner maintained 103(a) rejection. Applicants respectfully request the withdrawal of the rejection under 103(a) as obvious over Venter et al (application number 09/614,150). Since the 102(e) art is no longer applicable, the rejection under 103(a) should be withdrawn. Moreover, the examiner has acknowledged (on page 4, last paragraph) that the present application and application NO. 09/614, 150 has a common

assignee, thus, under 35 USC103(c), the 103 (a) rejection should be withdrawn because 103 (c) state that subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Rejection Under 35 USC § 101 Utility

The Examiner has rejected claims 4, 6, 8, and 22-26, as being drawn to polynucleotides encoding proteins of unidentified function. The Examiner has further stated that the claimed polynucleotides were not supported by either a specific or substantial asserted utility and that the specification fails to provide objective evidence of any activity for the encoded proteins or to show that these proteins even exist.

The examiner acknowledged that the cited utilities for developing insecticidal agents and for identifying vertebrate and invertebrate orthologs are credible.

However, the examiner stated that no well-established utilities for this specific SEQ ID Nos. 853-855 are identified in either the specification or in the cited prior art. In addition, no substantial utilities, which are specific to these nucleotide sequences and polypeptide encoded by these nucleotide sequences, are identified.

Applicants respectfully traverse these rejections based on the following remarks.

Contrary to the Examiner's assertions, the claimed isolated nucleic acid molecules, such as SEQ ID NOS: 853 and 854, that encode a specified amino acid sequence, SEQ ID NO: 855, and methods of making and using such nucleic acid molecules have several uses that meet the requirements of 35 U.S.C. §101. These, as well as the accepted state of the art view that such molecules have uses within the commercial marketplace in the insecticidal development cycles, since they encode previously unidentified members of important targets, establishes the utility of the claimed invention.

The utility requirement of a claimed invention requires that an invention must have a specific, substantial and credible utility. These requirements are defined in broad terms

in cases such as *Brenner v. Manson*, 148 USPQ 689 (S. Ct. 1966) and the recently adopted Utility Guidelines from the USPTO.

However, the notion that a recognized valuable addition to even entry points of insecticidal discovery cycle advances the art sufficient to establish a “usefulness” of a claimed invention should not be ignored. This is supported by previous case law (e.g., *Nelson v. Bowler*, 206 USPQ 881 (CCPA 1980)). Accordingly, the present invention, which is drawn to isolated nucleic acid molecules that encode a *Drosophila* survival protein (SEQ ID NO:855), has valuable commercial utilities in the insecticidal discovery process by providing previously unidentified members of an important agricultural target class. The present invention provides sufficient knowledge and information that is beneficial to the public, and provides sufficient guidance for researchers to use the claimed subject matter to develop fly killer. The present invention provides that P-element insertion produces a lethal phenotype. Thus the proteins such as SEQ ID NO: 855, are among the most essential proteins for *Drosophila* survival (see, e.g., page 3 of the specification). The P-element mutation has shown that these transcripts are essential for survival (see page 13 of the specification). Moreover, the public disclosure of a new member of the family through the patenting process clearly advances the art and augments the capabilities of agricultural research to combat insect caused disaster.

The utility rejection raised by the Examiner also conflicts with the case *Juicy Whip v. Orange Bang* (Fed. Cir. 1999). *Juicy Whip* held that, in order to violate the utility requirement, an invention must be “totally incapable of achieving a useful result.” The polypeptides and encoding nucleic acid molecules of the present invention are well known in the art to be valuable insecticidal targets and therefore have readily apparent commercial utilities, such as for screening potential small molecule compounds, producing antibodies, developing hybridization probes and primers, etc. Thus, for example, the proteins/nucleic acids of the present invention are commercially useful for developing insecticide for treating crops attacked by flies. Therefore, the present invention is not “totally incapable of achieving a useful result.” Instead, it is useful.

Thus, there is overwhelming evidence in the art to support the utility of novel *Drosophila* survival protein and encoding nucleic acid molecules. By placing a new

member of the *Drosophila* protein family into the public domain through the patenting process, the present invention is not only a clear advancement over the prior art (a newly discovered protein/gene) but also enables significant advancement in agriculture or other further discovery. The Utility requirement cannot be used to contradict the reasons for the patent system, i.e., to encourage early disclosures of inventions so that others can benefit from, improve upon, and further develop such inventions. This is particularly important in agriculture, wherein early disclosure of key inventions is needed to facilitate the early development of new agricultural treatment and disease preventions.

The grant of a patent to the claimed isolated nucleic acid molecule and the resultant disclosure of the nucleic acid and protein sequences to the public will certainly shorten the process for researchers to discover other novel uses for the present *Drosophila* protein-encoding nucleic acids. One example disclosed in the specification is that the present nucleic acid molecules can be used to produce protein targets for identifying agents that bind to the protein targets and modulate protein function. Such agents that bind to a protein target and modulate cellular processes such as cell signaling may subsequently be developed and refined for use in agricultural or other applications. All of this later discovery and refinement will be done using the presently claimed material. These uses are clearly commercial and substantial uses that are specific for a very limited number of proteins/nucleic acid molecules.

In view of law and fact, the utility standard interpreted by the USPTO guidelines is too high. Disclosure of experimental data or working examples in order to verify function is not required by any statute or case law interpreting the utility requirement of 35 U.S.C. §101. The evidence provided by Applicants, which is derived from analytical methods that are well-established in the art as being accurate and reliable, supporting the functional classification of the protein of SEQ ID NO:855 as an essential survival protein for *Drosophila*, together with the well-established commercial value of previously unidentified members of the *Drosophila* protein family, members of which are well known in the art to be commercially valuable drug targets and which have well-established functions and utilities, should be sufficient to satisfy the utility requirement. Therefore, applicants respectfully request that the Examiner withdraw the rejections.

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In view of the above, Applicants believe the present application is in the condition for allowance. Applicants respectfully request that the Examiner reconsider and withdraw the rejections of the claims, and issue a Notice of Allowance at the earliest convenience.

Respectfully submitted,
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